ATTACHMENT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: McIntyre et al.
Serial No. 10/526,228
Filed : November 16, 2005
For: *Whole Bacterial Cells as Immune Modulator*

Examiner: Swartz, Rodney P
Group Art Unit: 1645

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SUPPLEMENTAL RESPONSE

In response to the Office Action mailed July 30, 2007 and the Advisory Action mailed February 4, 2008, Applicants submit the following amendments and remarks in this request for reconsideration.

CLAIM AMENDMENTS

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. **(Cancelled)**

2. **(Cancelled)**

3. **(Currently Amended)** A pharmaceutical composition comprising isolated 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response.

Claims 4-7. **(Cancelled)**

8. **(Currently Amended)** A~~n immune modulator composition or a~~ pharmaceutical composition according to claim 3 for use as a medicament.

9. **(Currently Amended)** A~~n immune modulator composition or a~~ pharmaceutical composition according to claim 3 for use in or as a vaccine.

10. **(Currently Amended)** A~~n immune modulator~~ pharmaceutical composition according to claim 9 wherein said vaccine is a prophylactic vaccine or a therapeutic vaccine.

11. **(Cancelled)**

12. **(Currently Amended)** A~~n immune modulator composition and/or a~~ pharmaceutical composition according to claim 3 wherein said composition further comprises an antigen or antigenic determinant.

13. **(Currently Amended)** ~~An immune modulator composition and/or a~~ pharmaceutical composition according to claim 12 wherein said antigen or antigenic determinant is an antigen or antigenic determinant selected from one or more of a BCG (bacillus of Calmette and Guerin) vaccine, a diphtheria toxoid vaccine, a diphtheria/tetanus/pertussis vaccine, a pertussis vaccine, the tetanus toxoid vaccine, the measles vaccine, the mumps vaccine, the rubella vaccine, the OPV (oral poliomyelitis vaccine) and *Mycobacterium vaccae*, or part thereof.

14. **(Currently Amended)** ~~An immune modulator composition and/or~~ pharmaceutical composition according to claim 12 wherein said composition comprises two or more such antigens or antigenic determinants.

15. **(Currently Amended)** ~~An immune modulator composition and/or~~ pharmaceutical composition claim 3 wherein said bacterium is selected from the genus *Rhodococcus*.

16. **(Currently Amended)** ~~An immune modulator composition and/or~~ pharmaceutical composition according to claim 15 wherein said bacterium is one or more of the following *Rhodococcus ruber*, *Rhodococcus rhodococcus*, *Rhodococcus rhodnii*, *Rhodococcus coprophilus*, *Rhodococcus opacus* and *Rhodococcus erythopolis*.

17. **(Cancelled)**

18. **(Currently Amended)** A method for treating or preventing a condition in a subject comprising administering an effective amount of a ~~pharmaceutical~~ composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which ~~pharmaceutical~~ composition in use modifies a cellular immune response ~~and/or immune modulator composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides*, wherein said immune modulator composition in use modifies a cellular immune response to a subject~~.

19. **(Currently Amended)** A method for immunizing a subject comprising administering a ~~pharmaceutical~~ composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which ~~pharmaceutical~~ composition in use modifies a cellular immune response ~~and/or immune modulator composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides*, wherein said immune modulator composition in use modifies a cellular immune response~~.

20. **(Currently Amended)** A method according to claim 18 wherein said ~~pharmaceutical~~ composition ~~and/or an immune modulator composition~~ is co-administered with an antigen or antigenic determinant.

21. **(Original)** A method according to claim 20 wherein the antigen or antigenic determinant is an antigen or antigenic determinant selected from one or more of a BCG (bacillus of Calmette and Guerin) vaccine, a diphtheria toxoid vaccine, a diphtheria/tetanus/pertussis vaccine, a pertussis vaccine, a tetanus toxoid vaccine, a measles vaccine, a mumps vaccine, a rubella vaccine, a OPV (oral poliomyelitis vaccine) and *Mycobacterium vaccae*, or part thereof.

22. **(Currently Amended)** A method according to claim 20 wherein said ~~pharmaceutical~~ composition ~~and/or an immune modulator composition~~ is co-administered with two or more such antigens or antigenic determinants.

23. **(Currently Amended)** A method according to claim 19 wherein said ~~pharmaceutical~~ composition ~~and/or an immune modulator composition~~ is co-administered with an antigen or antigenic determinant.

24. **(Previously Presented)** A method according to claim 23 wherein the antigen or antigenic determinant is an antigen or antigenic determinant selected from one or more of a BCG (bacillus

of Calmette and Guerin) vaccine, a diphtheria toxoid vaccine, a diphtheria/tetanus/pertussis vaccine, a pertussis vaccine, a tetanus toxoid vaccine, a measles vaccine, a mumps vaccine, a rubella vaccine, a OPV (oral poliomyelitis vaccine) and *Mycobacterium vaccae*, or part thereof.

25. **(Currently Amended)** A method according to claim 23 wherein said ~~pharmaceutical~~ composition ~~and/or an immune modulator composition~~ is co-administered with two or more such antigens or antigenic determinants.

26. **(Currently Amended)** A~~n immune modulator composition and/or pharmaceutical~~ composition according to claim 13 wherein said composition comprises two or more such antigens or antigenic determinants.

27. **(New)** A method according to claims 18 or 19 wherein the composition is a pharmaceutical composition.

28. **(New)** A method according to claims 18 or 19 wherein the composition is an immune modulator composition.

REMARKS

Claims 3, 8-10, 12-16, 18-20, 22-23 and 25-26 have been amended. Support for the amendments can be found throughout the specification. No new matter has been added. Claim 17 has been cancelled. New claims 27 and 28 have been added. Support for the new claims can be found in the originally filed claims.

Applicants thank the Examiner for the telephonic interview on April 23, 2008, during which Applicants and the Examiner discussed proposed amendments to the claims.

Claims 3, 8-10, 12-16 and 18-28 are pending.

CLAIM REJECTIONS

Rejection under 35 U.S.C. § 101

The Examiner has maintained the rejection of claims 1-3, 8-10, 12-17 and 26 under 35 U.S.C. § 101 as being "directed to non-statutory subject matter." See Office Action at p. 2 and Advisory Action. Claims 8-10, 12-17 and 26 depend from independent claim 3.

Claim 3 relates to a pharmaceutical composition including isolated 10^4 to 10^{10} killed whole cells of a bacterium and a pharmaceutically acceptable carrier, diluent or excipient. Applicants respectfully submit that claim 3 does not read on naturally occurring bacteria. Applicants respectfully request the withdrawal of this rejection with respect to claim 3 and claims dependent therefrom.

Rejection under 35 U.S.C. § 102(b)

The Examiner has maintained the rejection of claims 1-3 and 8-10 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No 4,599,310 to Matson et al. ("Matson"). See Office Action at p. 2. Claims 1 and 2 have been cancelled thus rendering this rejection moot with respect to those claims. Claims 8-10 depend from independent claim 3.

Claim 3 relates to a pharmaceutical composition that includes isolated 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response.

Matson describes an antibiotic (sandramycin) produced by fermentation of a *Nocardioides* strain and further describes purifying sandramycin and the uses of this purified antibiotic. See col. 2, lines 58-60, col. 7, line 41 to col. 8, line 64, and col. 10, line 62 to col. 12, line 25. Matson describes cultivating cells for the production of an antibiotic. See col. 1, line 6 to col. 7, line 40. To extract the antibiotic, Matson describes that "[r]aw fermentation whole broth (~ 8 liters) was transferred to a 20-liter tank ..." and "[a]n equal volume of ethyl acetate was added." See col. 13, lines 25- 29 and flow chart depicting isolation of the antibiotic in cols. 7-8. Matson does not describe a pharmaceutical composition that includes isolated 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response.

Accordingly, independent claim 3 is not anticipated by Matson. Claims 8-10 depend from claim 3 and are also not anticipated by Matson for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 112

The Examiner has rejected claims 18-25 under 35 U.S.C. § 112, second paragraph for being indefinite "for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." See Office Action at p. 3. Claims 20-22 depend from independent claim 18 and claims 23-25 depend from independent claim 19. In an effort to expedite prosecution and not in acquiescence to any rejection, Applicants have amended claims 18 and 19.

Claim 18 relates to a method for treating or preventing a condition in a subject including administering an effective amount of a composition including 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which composition in use modifies a cellular immune response. Claim 19 relates to a method for immunizing a subject including administering a composition including 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and

Nocardioides and a pharmaceutically acceptable carrier, diluent or excipient, which composition in use modifies a cellular immune response.

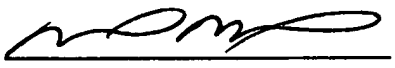
Applicants respectfully request the withdrawal of this rejection with respect to claims 18 and 19 and claims dependent therefrom.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. An Interview Summary is enclosed. Should any further fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 4-29-08



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STATEMENT OF SUBSTANCE OF INTERVIEW

Applicants thank the Examiner for the interview conducted with the Applicants' representative on April 23, 2008. During the Interview, Applicants' representative and the Examiner discussed proposed amendments to the claims to overcome the 35 U.S.C. § 101 and 112, second paragraph rejections. Applicants' representative and the Examiner also briefly discussed the 35 U.S.C. § 102(b) rejection.

The Statement of Substance of Interview is hereby filed within 30 days from the mailing date of the Interview Summary form. Should any fees be required by the present statement, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 4/29/08

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